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SEP 28 2006

Application No. 10/790,338

REMARKS

This Amendment is responsive to the Office Action dated June 16, 2006 and the advisory action dated August 15, 2006. The previous amendment submitted by the Applicant on August 14, 2006 was not entered by the Patent Office. The present Amendment is filed with a Request for Continued Examination, and entry of the present Amendment is requested.

Status of Claims

Claims 54-104 and 151-209 are pending. By this Amendment, claims 198, 207, and 208 are cancelled without prejudice. New claims 210 and 212 are directed to a coating only on a solid portion of the stent, e.g., as at page 18, lines 4-16. New claims 211 and 213 are directed to a coating applied on both a lumen and an exterior of a stent, e.g., as at page 18, line 1. New claims 214 and 215 specify a particular glass transition temperature, e.g., as at page 6, line 2. Claims 54, 151, and 190 are amended to specify an uncrosslinked copolymer, e.g., as at Examples 1-8 wherein no crosslinker was used to prepare or use the copolymer or coating; further explanation with respect to support is provided below. Claim 82 was amended for antecedent basis. Claims 97-99 and 170 are amended to specify the claimed glass transition temperature for the coating, e.g., as at page 12, lines 5-19 of the Application, and to clarify that differential scanning calorimetry relates to a measurement process, not a calculation process. Claim 151 is further amended to recite a coating, e.g., as at page 4, lines 4-14, and to delete "a composition associated with at least a portion of every". Claims 167, 170, and 206 are amended to delete the word "about". Claim 169 is amended for antecedent basis. Claim 190 is amended to delete "expandable stent".

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Amendments to Specification

The specification is amended as indicated to remove a formula for glass transition temperatures and a calculation thereof, and replaces it with the formula as described in the previously entered amendment. This present amendment does not raise 35 U.S.C. §112 issues since the deleted formula does not implicate the claimed glass transition temperatures taken by differential scanning calorimetry and because other formulas for calculating the same values are known to those skilled in the art. The formula written into the specification by the amendment is copied from column 7, lines 37-50 of U.S. Pat. No. 6,653,426, which patent is incorporated by reference into the Application at page 8 line 12 and page 49 line 10 of the Application.

ClaimsI. Request for Allowance of Claims 167, 170-189, 206, and new claims 214-215.

Claims 167, 170-182, and 206 stand rejected under 35 U.S.C. §103(a) in light of U.S. Pat. No. 6,530,950 (Alvarado) in combination with U.S. Pat. No. 5,637,113 (Tartaglia). Claims 183-185 stand rejected under 35 U.S.C. §103(a) in light of Alvarado in combination with Tartaglia and U.S. Pub. 2002/0133183 (Lentz). Amended claims 167, 170-189, and 206 are directed to a copolymer or coating with a glass transition temperature between 26 and about 40 degrees Centigrade. New claims 214 and 215 are directed to a **glass transition temperature of about 37°C**. In contrast, Alvarado teaches that an "the polymers of the inventions, as exemplified by those described in Tables 1-6, have glass transition temperatures *below* 25°C."

Claims 167, 170-182, and 206 are free of the prior art

The Office Action has rejected the indicated claims on the grounds that "about 26°C" reads on Alvarado. The amended claims delete the word "about" such that the claims are

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understood to be free of the prior art. This position is consistent with the most recent Office Action, wherein the Patent Office maintained that Alvarado read on the claimed invention because "about 26" read on temperatures below 26. As amended, the claims do not read on temperatures below 26.

Claims 167, 170-182, and 206 are supported in the specification

Claims 67, 170-189, and 206 have also been rejected under 35 U.S.C. §112¶1 for lack of support for the limitation "about 26°C". The Patent Office states that there is no explicit support for the claimed range. The Application states, however, at page 12, lines 15-19, that "Weighted Tg averages for copolymers and polymers as set forth herein include from . . . about 0°C to about 40°C. Persons of ordinary skill in these arts, after reading this disclosure, will appreciate that all ranges and values within these explicitly stated ranges are contemplated." This disclosure provides **explicit** support for all ranges and values from about 0°C to about 40°C, **including the claimed range** starting at 26 °C, such that 35 U.S.C. §112¶1 is explicitly satisfied.

The reasons of record for rejecting support of claims 167, 170-182, and 206 are directly contrary to established case law and are clearly erroneous.

The Examiner is respectfully reminded that, going forward, the burden of proof lies with the Patent Office to establish a written description rejection. As stated at MPEP 2163.04, a description as filed is **presumed** to be adequate, unless or until **sufficient evidence or reasoning to the contrary** has been presented by the examiner to rebut the presumption. The Patent Office has the **initial burden of presenting by a preponderance of evidence** why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. MPEP 2163.02 states that "The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that

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the inventor had possession at that time of the later claimed subject matter' “. The claimed invention is explicitly described over the claimed range and there is no reason to believe that Applicant did not possess the claimed range.

The Patent Office has taken the position that Applicant does not possess the claimed range because there is no literal support for the range and that its initial burden has been thereby been satisfied. Respectfully, this position is **directly contradictory to established case law** as explicitly stated in *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (CCPA, 1976): **“The PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of literal support alone were enough to support a rejection under §112, then the statement of *In re Lukach*, supra, 442 F.2d at 969, 58 CCPA at 1235, 169 USPQ at 796, that ‘the invention claimed does not have to be described in *ipsis verbis* in order to satisfy the description requirement of § 112,’ is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in *ipsis verbis* is insufficient.”** *In re Wertheim*, 541 F.2d 257, 265 (emphases added).

In re Wertheim directly addresses the present issue. The applicant's specification described a broad range of 25% to 60% solids. To avoid the prior art, the applicant claimed between 35% and 60% solids. The Patent Office maintained a written description rejection on the grounds that the claimed range lacked literal support. The court held that this position was wrong. *In re Wertheim*, 541 F.2d 257, 265. The court explained that “Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. As we said in a different context in *In re Saunders*, 444 F.2d 599, 607, 58 CCPA 1316, 1327, 170 USPQ 213, 220 (1971): To rule otherwise would let form triumph over substance, substantially

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eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed." In re Wertheim, 541 F.2d 257, 263.

The Patent Office's rejection is emphatically traversed. Allowance of claims 167, 170-189, 206, and new claims 214-215 is requested.

II. Claims rejected in light of Alvarado and Tartaglia

Claims 54-75, 77, 84, 92-104, 151-163, 167-182, 186-202, and 206-209 were rejected under 35 U.S.C. §103(a) for obviousness in light of U.S. Patent No. 6,530,950 (Alvarado) in view of U.S. Pat. No. 5,637,113 (Tartaglia). Tartaglia was cited to provide the claimed thickness. Claims 98, 207, and 208 have been cancelled.

A. Independent claims 54, 151, and 190 do not read on the cited references because the claimed copolymers are uncrosslinked

The rejection of claims 54-75, 77, 84, 92-104, 151-163, 167-169, 190-202, 206, and 209 is traversed on the grounds that the amended claims are directed to an uncrosslinked polymer that is not taught or suggested by the cited references.

Independent claims 54, 151, and 190 each recite the copolymer as "uncrosslinked". Since the copolymer is "uncrosslinked" it can not read on the crosslinked compositions in Alvarado, regardless of whether the claimed composition is bonded to an adjacent layer. The transition term "comprising" is open-ended but does not thereby allow the claim to recapture crosslinked copolymers since they are specifically excluded: if the claimed copolymers are crosslinked they are not what is claimed. The claimed copolymer is thus free of crosslinks and is free of Alvarado.

The term "uncrosslinked" is supported in the Application. As explained above, the Application describes many uncrosslinked embodiments, including working Examples. The

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presence of absence of a crosslinker has a very significant impact on polymeric structure. In the polymer arts, a composition would normally be free of crosslinkers unless they are specified. Thus the claims are directed to what the Applicant has described and what an artisan would understand them to possess as an invention at the time of filing. Certainly an artisan would not read the Application and take the opinion that the Applicants did not contemplate uncrosslinked compositions.

Indeed, Alvarado teaches using *crosslinked* compositions on a device. As taught at column 8, lines 1-17 of Alvarado, a variety of polymer compositions were prepared in the studies conducted in support of the Alvarado, each of which had a crosslinking agent, as shown in every Table and all the Examples. Alvarado explicitly teaches that there is **one alternative composition with no crosslinker**, see column 8, lines 1-17. In that sole embodiment, monomers are polymerized in a batch reactor in the absence of a crosslinker to form an intermediate product that is not used for a coating or device. Then the polymer is pelleted for feeding **along with the crosslinker** and crosslinked when used. The artisan reading Alvarado will understand that a crosslinker is intended for use in the Alvarado compositions.

A crosslinked polymer has structural and functional characteristics that make it distinct from an uncrosslinked polymer, including properties such as stiffness, strength, and elasticity. And, as explained below, crosslinked compositions generally do not have a glass transition temperature. Respectfully, it would be improper hindsight to apply the teaching of the Application to change the principle of operation of Alvarado to create the claimed coatings.

B. Claims 97-99, and independent claim 170 are free of the cited references because the claims specify a measured glass transition temperature, which is absent in the compositions in the cited references.

Claims 97-99 and independent claim 170 are directed to certain ranges of glass transition temperatures that are actual, measurable, glass transition temperatures. In contrast, the

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compositions of Alvarado are crosslinked. Crosslinking forms links between polymer chains and affects a variety of physical properties, e.g., elasticity and strength. As discussed in the attached disclosure entitled "Glass transition temperature", crosslinked compositions generally **do not have a glass transition temperature**. Significantly, at the bottom of the Table 1, column 8, line 40, Alvarado explains that the glass transition temperatures for crosslinked compositions were calculated, not measured. While the calculation scheme of Alvarado is presumably intended to guide artisans for creating the Alvarado compositions, there is nothing in Alvarado that suggests that actual, measurable, glass transition temperatures are achieved. In contrast, as taught in the Application, the claimed structures have actual glass transition temperatures that provide advantages with respect to therapeutic agent delivery, e.g., at page 21, lines 21-23, wherein the Application states that a significant factor to control agent release is to achieve a particular average glass transition temperature for agent-release applications in (or on) a patient's body. Since Alvarado's compositions do not have glass transition temperatures, these claims do not read on Alvarado

C. Alvarado does not teach or suggest the claimed coating.

The rejection of claims 54-75, 77, 84, 92-104, 151-163, 167-169, 190-202, 206, and 209 is further traversed on the grounds that, contrary to the Office Action, Alvarado does not teach or suggest the claimed coating. Instead, Alvarado teaches making a stent entirely from certain polymers, or using those polymers to make a sleeve to fit over a stent. In the Field of the Invention, Alvarado states that the invention relates to (i) a stent for insertion into a body lumen and (ii) a stent having a **polymer sleeve** formed of the disclosed compositions. The sleeve embodiment is set forth in Figure 3B, which is described at columns 12, lines 28-40 and quoted with added emphases as follows:

"FIG. 3B shows the metal stent of FIG. 3A with a continuous **polymer sheath 30** encasing the metal support stent. The **outer polymer sleeve** is prepared, for example, as set forth in Example 1, and is composed of a polymer composition described above,

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especially with respect to the compositions set forth in Tables 1-6. The sleeve is carried coaxially about the outer circumference of the support stent and takes the form of a flat sheet rolled into a cylindrical or tubular shape by overlapping the edges 32, 34 of the sheet. It will be appreciated that the initial configuration of the tubular member is not limited to a flat sheet, but can also be prepared from an extruded tube-form or from a molded tube-form."

Alvarado thus describes a sheath, sleeve, extruded tube-form and a molded-tube form. Alvarado does not, however, describe the claimed coating. The claimed coating is not the same as, and is not comparable to, the sleeve taught by Alvarado. For example, as explained in part in the Application at page 17, line 17 et seq., polymeric coatings are formed on an object. Forming the coating on the object gives rise to distinct physical properties at the material-to-device interface that are not present in a sleeve. A process of coating creates an intimacy of contact coating and the device that is often desirable. For instance, *paint* versus *siding* can both be options for covering an exterior surface of a dwelling. Paint forms a layer whereas siding is an overlay. The paint industry and the housing-siding industry provide different products with different advantages and disadvantages. Similarly, the claimed coating is distinct from the overlaying sleeve of Alvarado.

The other cited reference, Tartaglia, reinforces this same point because it is directed towards sleeves as opposed to the claimed coatings. Tartaglia teaches a film wrapped around a stent (column 1, line 45). A film wrapped around a stent is not the claimed coating and has distinct structural properties relative to a coating.

The rejection of amended claims 190-206 and 209 is further traversed on the grounds that the cited references do not teach or suggest the claimed devices.

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III. Regarding 35 U.S.C. §103(a) rejections made with Lentz et al.

Claims 76, 78-83, 85, 91, 164-166, 183-185, and 203-205 were rejected under 35 U.S.C. §103(a) as being unpatentable over Alvarado in view of Tartaglia and U.S. Pat. Pub. No. 2002/0133173 to Lentz et al. Lentz et al., however, does not make-up for the deficiencies of Alvarado and Tartaglia that are discussed above. Moreover, Alvarado is directed to a sleeve that fits over a stent such that coating the sleeve of Alvarado with heparin of Tartaglia would not result in an operable invention since the heparin would be outside the stent and effectively not in contact with blood flowing through the lumen of the stent, thus defeating the point of adding a heparin layer. Allowance of these claims is therefore requested.

IV. Regarding 35 U.S.C. §103(a) rejections made with Sahatjian et al.

Claims 86-90 were rejected under 35 U.S.C. §103(a) in light of Alvarado in combination with Tartaglia and U.S. Pat. No. 5,843,089 to Sahatjian et al. Sahatjian et al., however, does not make-up for the deficiencies of Alvarado and Tartaglia that are discussed above. Further, Sahatjian et al. is directed to a hydrogel lining on a stent lumen and not an exterior sleeve, as in Alvarado. Nor would there be a reasonable expectation of success when adding a hydrogel to the compositions of Alvarado since a hydrogel has radically different physical properties than Alvarado's compositions, which are believed to exclude hydrogels. Moreover, coating the exterior sleeve of Alvarado with the hydrogel of Sahatjian et al. would not result in an operable invention since the hydrogel lining would be outside the stent and effectively not in contact with blood flowing through the lumen of the stent, thus defeating the point of having the hydrogel liner as stated in Sahatjian et al.

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V. Regarding new claims 210-213

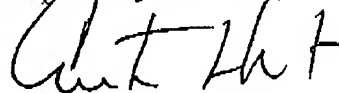
It is respectfully submitted that Alvarado teaches a sleeve on an exterior portion of a stent and does not teach or suggest the claimed coating on both a lumen and an exterior of the stent (claims 211, 213). It is further submitted that Alvarado teaches a sleeve that indiscriminately covers the gaps in the mesh of the stent such that it does not teach or suggest the claimed coating is disposed essentially only on the solid portions of the stent (claims 210, 212). Nor do the other cited references cure these deficiencies when considered in light of the other claimed features. Allowance of new claims 210-213 is accordingly requested.

Prayer for relief

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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